REMARKS

1. Formal Matters

a. Status of the Claims

Claims 21-40 are pending in this application. Claims 21, 23-25, 27, 28, 35, and 36 are amended. In order to expedite prosecution and without prejudice to seeking claims with similar scope, claims 22, 26, 29-34, and 37-40 are hereby canceled. Upon entry of these amendments, claims 21, 23-25, 27, 28, 35, and 36 are pending and under active consideration. Applicant respectfully requests entry of the amendments and remarks made herein into the file history of the present application.

b. Amendments to the Claims

Claim 21 is amended to recite an isolated nucleic acid consisting of X nucleotides, wherein X=18 to 120, which is rephrasing of the limitation "An isolated nucleic acid consisting of 18 to 120 nucleotides" of previously-presented claim 21. This amendment is not being made for any reasons of patentability and does not change the claim scope.

Claim 21 is also amended to recite that the sequence of the nucleic acid comprises at least Y consecutive nucleotides of SEQ ID NOs: 128, 131, or 133, wherein Y≥18, and wherein X≥Y. Support for this amendment can be found at Table 1, lines 892-898, 913-919, and 927-933, and paragraphs 1943, 1985, and 2013 of the application as originally filed. Table 1 discloses SEQ ID NOs: 128, 131, and 133, which are the sequences of VGAM142, VGAM145, and VGAM147, respectively, as follows:

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GENE     PRECURSOR-SEQUENCE   P-SEQID GENE-SEQ   G-SEQID FOLDED PRECURSOR
======== ==================== ======= ========== ======= ================================================
GAM142   CACCGCCTCTAGATATCGCC 128     CGCCTTTATT 477        CG         ATCG--  TTTAT    ACATT       AAATCCA
         TTTATTTCCACATTAGATGG         TCCACATTAG         CAC  CCTCTAGAT      CC     TTCC     AGATGGT       A
         TAAATCCAATAGTGAAACTA         ATGG               |||  |||||||||      ||     ||||     |||||||
         TCTTTTTAGGAATGTATGGA                            GTG  GGAGATTTG      GG     AAGG     TCTATCA       /
         CTCGCGTTTAGAGGAGTG                                 A-         CGCTCA  TATGT    ATTTT       AAGTGAT


GAM145   GGCTATTCTGGCGGCTAGAA 131     TGCTATTTCG 480          C            TA        TAAT   GA   TGT
         TGGCATAATCCGGATGTTGT         GCTGCCAGAG         GG TATTCTGGCGGC  GAATGGCA    CCG  TGT   G
         GTAGTACAAGTGGCTGCTAT         TGTC               || ||||||||||||  ||||||||    |||  |||
         TTCGGCTGCCAGAGTGTCC                             CC GTGAGACCGTCG  TTTATCGT    GGT  ACA   T
                                                           T            GC        C---   GA   TGA

GAM147   TCTGGTTCTATGTTCCTCGT 133     TCTATGTTCC 482          TC   ---        TT  C  TATT
         TTCCTGTATTCTTTTTAAGA         TCGTTTCCTG         TCTGGT  TAT   GTTCCTCG  TC TG    C
         TCGAGGAACGCCATAATATC         TATT               ||||||  |||   ||||||||  || ||
         AGA                                             AGACTA  ATA   CAAGGAGC  AG AT    /
                                                               TA   CCG        T-  A  TTTT
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Additionally, for the Examiner's convenience, Applicant submits herewith Exhibit A, which depicts the relationships of the claimed polynucleotide sequences to the sequence of the gene that encodes VGAM142, VGAM145, and VGAM147 (SEQ ID NO: 3760).

Claim 21 is further amended to recite that the nucleic acid comprises a sequence at least 67.7% identical to the nucleic acid of limitations (a) or (b). This is a rephrasing of the ratio "42/63" of previously-presented claim 21, which when expressed as a percentage is equivalent to 67.7%. This amendment is not being made for any reasons of patentability and does not change the claim scope.

Claim 23 is amended to recite the phrase "X nucleotides of the nucleic acid are of a sequence selected from the group consisting of SEQ ID NOs: 477, 480, and 482," which is a rephrasing of the limitation "wherein the at least 18 nucleotides is of a sequence selecting from the group consisting of SEQ ID NOS: 477, 480, and 482," of previously-presented claim 23 and which has antecedent basis in amended claim 21. Claim 23 is also amended to correct a typographical error of the word "selected." These amendments are not being made for any reasons of patentability and do not change the claim scope. For the Examiner's convenience, Applicant refers the Examiner to Exhibit A, which describes the relationship of SEQ ID NOS: 477, 480, and 482, to SEQ ID NOs: 128, 131, 133, and to SEQ ID NO: 3760.

Claim 24 is amended to recite the nucleic acid wherein X=18 to 24, which is a rephrasing of the limitation "wherein the nucleic acid consists of 18 to 24 nucleotides" of previously-presented claim 24 and which has antecedent basis in amended claim 21. This amendment is not being made for any reasons of patentability and does not change the claim scope.

Claim 25 is amended to recite the nucleic acid wherein X=Y, which is rephrasing of the limitation "the sequence of the nucleic acid consists of," of previously-presented claim 25 and which has antecedent basis in amended claim 21. This amendment is not being made for any reasons of patentability and does not change the claim scope.

Claim 27 is amended to recite the nucleic acid of claim 23, wherein X=Y, which is a rephrasing of previously-presented claim 27, and which has antecedent basis in amended claim 21. This amendment is not being made for any reasons of patentability and does not change the claim scope.

Claim 28 is amended to recite the nucleic acid wherein X=18 to 24, which is a rephrasing of the limitation "the nucleic acid consists of 18 to 24 nucleotides" of previously-presented claim 28 and which has antecedent basis in amended claim 21.

Claim 35 is amended to recite a vector comprising the nucleic acid of claim 21, which is a rephrasing of previously-presented claim 35 and which has antecedent basis in amended claim 21. This amendment is not being made for any reasons of patentability and does not change the claim scope.

Claim 36 is amended to recite a vector comprising the nucleic acid of claim 25, which is a rephrasing of previously-presented claim 36 and which has antecedent basis in amended claim 25. This amendment is not being made for any reasons of patentability and does not change the claim scope.

c. Amendments to the Specification

The specification is amended to strike the term "novel" from the title, as required by the Examiner.

d. Amendments to the Abstract

The abstract is amended to strike the term "novel," as required by the Examiner

2. Preliminary Remarks

a. Oath/Declaration

On page 2 of the Office Action, the Examiner requires a new oath or declaration because the application allegedly presents a claim for subject matter not originally claimed or embraced in the statement of the invention. The Examiner asserts that a new matter allegedly has been entered into all pending claims in the amendments filed for the instant application on September 13, 2006, and September 21, 2006 based on a new matter rejection under 35 U.S.C. § 112 described below.

Applicant respectfully disagrees. Applicant respectfully submits that a "Supplement to Replacement Sequence Listing Under 37 C.F.R. § 1.825(a) Filed September 13, 2006," which was filed on September 21, 2006 ("Supplemental Letter," hereafter), entered SEQ ID NO: 3760 into the application. Applicant additionally submits that the Supplemental Letter demonstrates that SEQ ID NO: 3760 is supported by the application as filed and included a statement that amending the sequence listing to include SEQ ID NO: 3760 does not enter new matter to the application.

In view of the foregoing, Applicant respectfully submits that no new matter has been entered. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the requirement for a supplemental oath or declaration.

b. Objection of Priority to SEQ ID NO: 3760 in the Priority Application

At page 3 of the Office Action, the Examiner alleges that U.S. Provisional Application No. 60/441,241 (the "Priority Application" hereafter) fails to provide adequate support or enablement for the sequence set forth in SEQ ID NO: 3760. The Examiner further asserts that VGR389, which includes SEQ ID NO: 3760, does not exist in the Priority Application. Accordingly, the Examiner denies benefit of the Priority Application filing date to SEQ ID NO: 3760.

Applicant respectfully disagrees. Applicant respectfully submits that VGR389 of the instant application is labeled as GR26 in the Priority Application. The description of GR26 is located on a CD that was submitted with the Priority Application on January 17, 2003. In one of the CDs, a file designated "cluster file 000364-000399.txt" at lines 267-278 discloses that GR26 folded precursor RNA is processed, to form hairpin sequences VGAM142, VGAM145, and VGAM147 (amongst others). The files entitled "fig-000142_0001.tif," "fig-000145_0001.tif," and "fig-000147_0001.tif" disclose that VGAM142, VGAM145, and VGAM 147 have the same sequences as the instant claimed VGAMs. Therefore,

Applicant respectfully requests that priority be reestablished for SEQ ID NO: 3760 to the Priority Application.

c. Specification

On page 4 of the Office Action, the Examiner objects to the term "novel" in the title of the application and in the abstract and requires appropriate correction. Applicant respectfully submits that the specification and abstract have been amended to strike this term. Accordingly, Applicant respectfully requests that this objection be reconsidered and withdrawn.

d. Claim Objections

On page 4 of the Office Action, the Examiner objects to claims 22-24 under 37 C.F.R. § 1.75 as being substantial duplicates of claims 26-28, respectively. Applicant respectfully disagrees. As discussed above, claims 22 and 26 are canceled without prejudice. Applicant further submits that in view of the amendments to claims 23, 24, 27, and 28, the subject matter of each claim differs in scope and is not substantially duplicated by another claim. Applicant notes that claims 22 and 26 are canceled without prejudice. In view of the foregoing amendments and remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the objection to claims 22-24 and 26-28.

3. Patentability Remarks

a. 35 U.S.C. § 101

Claims 21-34

At page 5 of the official action, the Examiner rejects claims 21-34 under 35 U.S.C. §101, for allegedly lacking utility. In order to satisfy the utility requirement under the Revised Interim Utility Guidelines, a specific and substantial utility must either (i) be cited in the specification, or (ii) be recognized as well established in the art, and the utility must be credible.

(1) Specific Utility

A specific utility is defined in the Revised Interim Utility Guidelines Training Materials ("RIUGTM") as a utility that is specific to the particular claimed subject matter, which is in contrast to a general utility that would be applicable to a broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" is not considered to be specific in the absence of a disclosure of a specific DNA target. *See* RIUGTM at page 5.

At page 5 of the office action, the Examiner alleges that the disclosed uses of the claimed nucleic acids are not specific and are generally applicable to any nucleic acid. Applicant respectfully disagrees. The specification identifies **specific** genes of interest that the claimed polynucleotides may be used to regulate expression.

At paragraphs 1948 and 1949 of the specification, it is asserted that the disclosed polynucleotides may be used to target and modulate expression of particular mRNA transcripts. Furthermore, paragraphs

1940, 1941, 1951, and 1953 of the specification disclose that the claimed polynucleotides, which are related to the miRNA encoded by the GAM142 gene, modulate expression of particular target mRNA transcripts as shown in Table 2. Table 2 discloses that ACADSB, C20orf170, DORFIN, FLJ21313, KIAA1819, LOC127002, LOC132332, LOC145624, P37NB, RAP140, and ZNF26 are specific target genes for the miRNA related to claimed polynucleotides (SEQ ID NOS: 128 and 447).

At paragraphs 1990 and 1991 of the specification, it is asserted that the disclosed polynucleotides may be used to target and modulate expression of particular mRNA transcripts. Furthermore, paragraphs 1982, 1983, 1994, and 1995 of the specification disclose that the claimed polynucleotides, which are related to the miRNA encoded by the GAM145 gene, modulate expression of particular target mRNA transcripts as shown in Table 2. Table 2 discloses that INHBA, TBXAS1, KIAA1056, LOC197342, and LOC91752 are specific target genes for the miRNA related to claimed polynucleotides (SEQ ID NOS: 131 and 480).

At paragraphs 2018 and 2019 of the specification, it is asserted that the disclosed polynucleotides may be used to target and modulate expression of particular mRNA transcripts. Furthermore, paragraphs 2010, 2011, 2022, and 2023 of the specification disclose that the claimed polynucleotides, which are related to the miRNA encoded by the GAM147 gene, modulate expression of particular target mRNA transcripts as shown in Table 2. Table 2 discloses that ATP10C, CASP10, DORFIN, FLJ21313, KIAA1819, LOC127002, LOC132332, LOC14562, P37NB, RAP140, and ZNF36 are specific target genes for the miRNA related to claimed polynucleotides (SEQ ID NOS: 1331 and 482). Accordingly, Applicant respectfully submits that the specification provides a specific utility for the claimed polynucleotides.

(2) Substantial Utility

A substantial utility is defined in the RIUGTM as a utility that defines a "real world" use, which is in contrast to the need to carry out further research to identify or confirm a "real world" context. As discussed above, the claimed GAM142 polynucleotides may be used to regulate expression of proteins encoded by ACADSB, C20orf170, DORFIN, FLJ21313, KIAA1819, LOC127002, LOC132332, LOC145624, P37NB, RAP140, and ZNF26. These GAM142 targeted genes are linked to particular disease states or essential biological functions. For example, the Priority Application and Andresen et al., Am. J. Human Genetics 67:1095-1103 (2000), which is submitted on the Information Disclosure Statement filed herewith, discloses that the gene ACADSB is known to be associated with the disease 2-

methylbutyryl-CoA dehydrogenase deficiency, an autosomal recessive disorder of L-isoleucine metabolism.[1]

The claimed GAM145 polynucleotides may be used to regulate expression of proteins encoded by INHBA, TBXAS1, KIAA1056, LOC197342, and LOC91752. These genes are also linked to particular disease states or essential biological functions. For example, Priority Application and Brown et al., Nature Genetics 25:453-457 (2000), which is submitted on the Information Disclosure Statement filed herewith, discloses that mutations in the target gene INHBA lead to development defects.[2]

The claimed GAM147 polynucleotides may be used to regulate expression of proteins encoded by ATP10C, CASP10, DORFIN, FLJ21313, KIAA1819, LOC127002, LOC132332, LOC14562, P37NB, RAP140, and ZNF36. These genes are also linked to particular disease states or essential biological functions. For example, Priority Application and Shin et al., Blood 99:4094-4099 (2002), which is submitted on the Information Disclosure Statement filed herewith, discloses that the target gene CASP10 are involved in the development of non-Hodgkin lymphoma.[3] One of ordinary skill in the art would recognize that the claimed polynucleotide may be used to regulate expression of genes of interest such as ACADSB, INHBA, and CASP10. Accordingly, Applicant respectfully submits that the specification provides a substantial utility for the claimed polynucleotides.

(3) Credible Utility

According to the RIUGTM, an asserted utility is credible if the assertion is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided. An assertion is credible unless (i) the logic underlying the assertion is seriously flawed, or (ii) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. See RIUGTM at page 5.

At page 5 of the Office Action, the Examiner asserts that the asserted uses described in the instant specification are generally applicable to a myriad of isolated nucleic acids. Applicant respectfully disagrees.

Applicant respectfully submits that the Examiner has not considered the asserted utility as discussed above for using the claimed polynucleotides for modulating expression of **specific mRNA targets**. Whether or not the claimed polynucleotides actually exist in a biological system, and could be

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[1] Disclosure of the function of ACADSB can be found in CD file PALs 000100-000199.txt, between lines 2251 to 2325.

[2]Disclosure of the function of ACADSB can be found in CD file PALs 000100-000199.txt, between lines 2407 to 2449.

[3]Disclosure of the function of ACADSB can be found in CD file PALs 000100-000199.txt, between lines 2468 to 2517.

used as a probe, a neutralizing agent of viral RNA, or preventing or treating viral diseases are irrelevant. The proper inquiry is instead whether a person of ordinary skill in the art would believe that the claimed polynucleotides **may be** used to modulate expression of **the specific mRNA targets**.

Paragraph 0120 of the application discloses that the mRNA targets of the claimed polynucleotides were identified as being consistent with the free energy and spatial structure of target binding sites of known miRNAs. The method as described in paragraph 0120 for identifying target binding sites of miRs is based upon studies at the time of filing demonstrating that miRs bind to target binding sites as disclosed in references such as Wightman *et al.* (1993), Reinhart *et al.* (2000), Slack *et al.* (2000), Lau *et al.* (2001), Lagos-Quintana *et al.* (2001), and Moss *et al.* (1997), which are all cited in the Information Disclosure Statement filed October 3, 2006 under reference numbers 30, 260, 300, 780, 790, and 100, respectively. In view of the asserted utilities being consistent with the general understanding of miRNAs and their target binding sites at the time of filing, Applicant respectfully submits that one of ordinary skill in the art would believe that each claimed polynucleotide would bind its respective target binding sites.

In view of the foregoing remarks and lack of showing that Applicant's assertion of utility is seriously flawed or logically inconsistent, the Applicant respectfully submits that a credible utility is asserted for the claimed polynucleotides.

Claims 39 and 40

At pages 5 and 6 of the Office Action, the Examiner rejects claims 39 and 40 under 35 U.S.C. §101, for allegedly embracing two different statutory classes of an invention. Specifically, the Examiner asserts the claims are directed to neither a "process" nor a "machine," but embraces both of these statutory classes of invention.

As discussed above, Applicant has canceled claims 39 and 40 without prejudice thereby rendering the utility rejection moot. In view of the foregoing amendment, Applicant respectfully requests that the rejection of claims 39 and 40 under 35 U.S.C. § 101 for embracing two different statutory classes be reconsidered and withdrawn.

b. 35 U.S.C. § 112, second paragraph

Claims 39 and 40

On page 6 of the Office Action, the Examiner rejects claims 39 and 40 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Applicant respectfully notes that claims 39 and 40 are canceled without prejudice, thereby rendering the rejection moot.

Claims 21 and 25

On pages 6-7 of the Office Action, the Examiner rejects claims 21-40 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. The Examiner asserts that it is unclear what constitutes the

sequence recited in claims 21 (c) and 25 because the numerical value "42/63" of is not properly defined in the instant specification.

Applicant respectfully disagrees. Applicant submits that The ratio "42/63" corresponds to the number of complementary base pairs within the stem loop structure of the nucleotide sequence as set forth in SEQ ID NO: 133. Support for the ratio 42/63 can be found at Table 1, lines 927-933 as follows:

```
GENE     PRECURSOR-SEQUENCE   P-SEQID GENE-SEQ   G-SEQID FOLDED PRECURSOR
======== ==================== ======= ========== ======= ================================================
GAM147   TCTGGTTCTATGTTCCTCGT 133     TCTATGTTCC 482           TC   ---        TT  C  TATT
         TTCCTGTATTCTTTTTAAGA         TCGTTTCCTG         TCTGGT  TAT   GTTCCTCG  TC TG    C
         TCGAGGAACGCCATAATATC         TATT               ||||||  |||   ||||||||  || ||
         AGA                                             AGACTA  ATA   CAAGGAGC  AG AT    /
                                                               TA   CCG        T-  A  TTTT
```

Applicant respectfully submits that one of ordinary skill in the art would clearly recognize that this degree of complementarity can be described as a ratio and corresponds to the amount of variance allowed in the disclosed nucleic acid sequences. Nevertheless, in order to expedite prosecution of the instant application, claim 21 has been amended to recite this ratio as an equivalent percentage (*i.e.*, 67.7%), as described above (See Section 1.b). Applicant additionally notes that amended claim 25 recites neither the ratio 42/63 nor the percentage 67.7%. Accordingly, in view of the foregoing amendments and remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 21 and 25.

Claims 33 and 34

The Examiner also alleges that the ratio "15/25" of claims 33 and 34 is indefinite. Applicant respectfully disagrees. Applicant submits that the ratio "15/25" corresponds to the number of complementary bases between the claimed nucleic acids and a target binding site as described in Table 2, lines 7203-7282, as follows:

```
GENE     TARGET    UTR SEQUENCE               SEQID   BINDING-SITE
======== ========= === ====================== ======= ============================
GAM142   SDCCAG16  3'  CATTTTAAAAATAAAGGC     1316              CCACATT
                                                      GCCTTTATTT       AGATG
                                                      ||||||||||       |||||
                                                      CGGAAATAAA       TTTAC
                                                                AAT____
```

As shown above, Table 2 discloses that the miRNA that is formed by VGAM142 and corresponds to SEQ ID NO: 477, is capable of binding the target gene SDCCAG16 with 15 complementary bases out of 25 bases of SEQ ID NO: 477. This degree of complementarity expressed as a ratio, is 15/25. Nevertheless, claims 33 and 34 have been canceled without prejudice thereby rendering the rejection moot.

Claim 21

The Examiner further alleges that claim 21 is ambiguous and internally inconsistent because of the phrase "An isolated nucleic acid consisting of 18 to 120 nucleotides wherein the sequence of the nucleic acid comprises:" (the "Consistory Phrase" hereafter). The Examiner asserts that this phrase contains two conflicting transitional terms.

Applicant respectfully disagrees. Applicant notes that the Consistory Phrase has been amended to recite that the nucleic acid consists of X nucleotides, wherein X=18 to 120. This amendment has not changed the scope of the claim. Nevertheless, Applicant respectfully submits that the limitations "consisting of X nucleotides" and "wherein X=18 to 120" describe the length of the claimed nucleic acid. Thus, the nucleic acid is between 18 to 120 nucleotides (inclusive) and can not include any other element.

Applicant further submits that the transitional phrase "comprises" in claim 21 sets forth the sequences that can be included within the sequence of the nucleic acid that is between 18 to 120 nucleotides in length. Hence, the nucleic acid of claim 21 can include Y consecutive nucleotides (wherein $Y \geq 18$) of SEQ ID NOs: 128, 131, 133, an RNA equivalent thereof, a sequence at least 67.7% identical thereto, or the complement thereof. Applicant respectfully submits that the phrase "consisting of" sets the upper limit of the length of the included sequences to 120 nucleotides. For example, a nucleic acid of claim 21 comprising all of SEQ ID NO: 128 would include 98 nucleotides of SEQ ID NO: 128 and could include as many as zero to 22 additional nucleotides.

Accordingly, Applicant respectfully submits that the limitations "consisting of" and "comprising" in claim 21 do not conflict. In view of the foregoing amendments and remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claim 21.

Claims 26, 27, 30, 32, and 34

On page 8 of the Office Action, The Examiner rejects claims 26, 27, 30, 32, and 34 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Examiner asserts that the limitation "the at least 18 nucleotides" in claims 26 and 27 does not have antecedent basis in claim 25. Applicant notes that amended claim 27 does not recite this limitation. Applicant further notes that claim 26 has been canceled without prejudice, thereby rendering the rejection of claim 26 moot. Accordingly, in view of the foregoing amendments and remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 26, 27, 30, 32, and 34 under 35 U.S.C. § 112, second paragraph.

Claims 29 and 30

On page 8 of the Office Action, the Examiner rejects claims 29 and 30 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Applicant notes that claims 29 and 30 are canceled without prejudice, thereby rendering the rejection moot.

c. 35 U.S.C. § 112, first paragraph

Claims 21-34

On pages 8-9 of the office Action, the Examiner rejects claims 21-34 under 35 U.S.C. § 112, first paragraph for allegedly not being supported by either a specific utility or a well-established utility. Applicant respectfully disagrees. In view of the foregoing remarks (See 3.a above), Applicant has requested that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 101. Accordingly, Applicant respectfully requests that the Examiner also reconsider and withdraw the rejection of claims 21-34 under 35 U.S.C. § 112, first paragraph.

Claims 39 and 40

On pages 9-11 of the Office Action, the Examiner rejects claims 39 and 40 under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the enable requirement. Applicant respectfully notes that claims 39 and 40 are canceled without prejudice, thereby rendering the rejection moot.

Claims 21-40

On pages 11-12 of the Office Action, the Examiner rejects claims 21-40 under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement because the elected invention SEQ ID NO: 3760 introduces new matter. Applicant respectfully disagrees. As described above, Applicant respectfully notes that on September 21, 2006, Applicant submitted the Supplemental Letter described above, which requested amendment of the sequence listing to include SEQ ID NO: 3760, which is a part of the sequence of VGR389, and established that SEQ ID NO: 3760 has written description support in the application as filed. Nevertheless, reference to SEQ ID NO: 3760 has been removed from the claimed subject matter thereby rendering the rejection of claims 21-40 under 35 U.S.C. § 112, first paragraph moot.

d. 35 U.S.C. § 102

(1) 35 U.S.C. § 102(b), claims 21 and 35

On page 12 of the Office Action, the Examiner rejects claims 21 and 35 under 35 U.S.C. § 102(b) as allegedly being anticipated by Paoletti et al. (US 5,744,140, "Paoletti" hereafter). The Examiner asserts that Paoletti teaches SEQ ID NO: 23, of which nucleotides 18-58 perfectly align with nucleotides 994-1034 of the instant SEQ ID NO: 3760, thus meeting the minimal structural requirement of consisting of at least 18 consecutive nucleotides of SEQ ID NO: 3760.

Applicant respectfully disagrees in view of the amendments to the claims. For the Examiner's convenience, Exhibit A submitted herewith shows the relationship between the sequences as set forth in

SEQ ID NOS: 128, 131, 133, 477, 480, 428, and 3760 of the instant application with the cited sequence of Paoletti (SEQ ID NO: 23).[4]

Applicant respectfully submits that amended claim 21 is directed in part to a nucleic acid consisting of X nucleotides (where X is 18 to 120) wherein the sequence of the nucleic acid comprises SEQ ID NOS: 128, 131, or 133; or a sequence at least 67.7% identical to SEQ ID NOS: 128, 131, or 133. As shown in Exhibit A, Applicant submits that the sequence as set forth in SEQ ID NO: 23 of Paoletti does not overlap nor fall within the range of variance of SEQ ID NOS: 128, 131, or 133. Similarly, Paoletti does not teach a vector comprising the nucleic acid of claim 21. In view of the foregoing amendment and remarks, Applicant respectfully submits that the rejection of claims 21 and 35 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

(2) 35 U.S.C. § 102(e), claims 21, 24, 28, 37, and 38

On pages 12 and 13 of the Office Action, the Examiner rejects claims 21, 24, 28, and 37-38 under 35 U.S.C. § 102(e) as allegedly being anticipated by Zhou (US 2004/0146910 A1, "Zhou" hereafter). The Examiner asserts that Zhou teaches SEQ ID NO: 213,554, of which 18 consecutive nucleotides perfectly align with 18 consecutive nucleotides of instant SEQ ID NO: 3760.

Applicant respectfully disagrees in view of the amendment to the claims. For the Examiner's convenience, submitted Exhibit A shows the relationship between the sequences as set forth in SEQ ID NOS: 128, 131, 133, 477, 480, 428, and 3760 of the instant application with the cited sequence of Zhou (SEQ ID NO: 213,554).

As discussed above amended claim 21 is directed in part to a nucleic acid consisting of X nucleotides (where X is 18 to 120) wherein the sequence of the nucleic acid comprises SEQ ID NOS: 128, 131, or 133; or a sequence at least 67.7% identical to SEQ ID NOS: 128, 131, or 133. As shown in Exhibit A, Applicant submits that the sequence as set forth in SEQ ID NO: 213,554 of Zhou does not overlap nor fall within the range of claim variance of SEQ ID NOS: 128, 131, or 133.

In view of the foregoing, Zhou neither teaches nor suggests all the limitations of amended claim 21. Claims 24 and 28 draw their dependency from claim 21 and therefore are not anticipated by Zhou. As discussed above, claims 37 and 38 have been canceled without prejudice. Accordingly, in view of the foregoing amendments and remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 21, 24, 28, 37, and 38 under 35 U.S.C. § 102(e).

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[4] Please note that Xs designate nucleotides of the prior art sequence that do not align with any nucleotides of a sequence of the instant application..

4. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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